

REMARKS**Inventions**

In the Restriction Requirement dated September 7, 2006, the Examiner requires election of one of the following inventions:

Group I, claim(s) 1-45, drawn to a method for preserving a biomaterial/mammalian cell in which the transporter protein is a glucose transporter protein.

Group II, claim(s) 1-13, 15, 16, 19-26, 28, 29, 32-38, 40, and 43-45, drawn to a method for preserving a biomaterial/mammalian cell in which the transporter protein is a sucrose transporter protein.

Group III, claim(s) 1-13, 15, 16, 19-26, 28, 29, 32-38, 40, and 43-45, drawn to a method for preserving a biomaterial/mammalian cell in which the transporter protein is a mannose transporter protein.

Group IV, claim(s) 1-13, 15, 16, 19-26, 28, 29, 32-38, 40, and 43-45, drawn to a method for preserving a biomaterial/mammalian cell in which the transporter protein is a galactose transporter protein.

Group V, claim(s) 1-13, 15, 16, 19-26, 28, 29, 32-38, 40, and 43-45, drawn to a method for preserving a biomaterial/mammalian cell in which the transporter protein is a hexose transporter protein.

Group VI, claim(s) 46-57, drawn to a mammalian cell prepared for preservation comprising a non-metabolizable carbohydrate and a glucose transporter protein.

Group VII, claim(s) 46, 47, 49 and 52-57, drawn to a mammalian cell prepared for preservation comprising a non-metabolizable carbohydrate and a sucrose transporter protein.

Group VIII, claim(s) 46, 47, 49 and 52-57, drawn to a mammalian cell prepared for preservation comprising a non-metabolizable carbohydrate and a mannose transporter protein.

Group IX, claim(s) 46, 47, 49 and 52-57, drawn to a mammalian cell prepared for preservation comprising a non-metabolizable carbohydrate and a galactose transporter protein.

Group X, claim(s) 46, 47, 49 and 52-57, drawn to a mammalian cell prepared for preservation comprising a non-metabolizable carbohydrate and a hexose transporter protein.

Specifically, the Examiner states:

The requirement of unity of invention is not fulfilled because there is no technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features.

The inventions of Groups I-X, do not share the common special technical feature of the set of three components that are a mammalian cell or biomaterial, a transporter molecule (transporter protein) and a preservation agent transported by the transporter molecule because Curtis (US 2003/0009024 A1) discloses human cells comprising a membrane transport protein designated 65484. This transport protein transports a variety of molecules, such as hexoses, disaccharides, hormones, peptides and neurotransmitters across the cell membrane, and this transport serves to preserve the cell by maintaining normal metabolism and health of the cell (see paragraphs 9, 71, 77, and 157). To preserve cells in which this transport protein is lacking or in which this transport mechanism is deficient, the gene for the transport protein may be cloned into a mammalian expression vector and expressed at the DNA and protein levels in mammalian cells (see paragraphs 206-215). As the human diet contains sugars and peptides, either ingested or as digestion products, and as humans consume pharmaceutical compositions, these compounds come in contact with the cell membranes.

Thus, the technical feature of a mammalian cell comprising the set of three components that are a mammalian cell or biomaterial, a transporter molecule (transporter protein) and a preservation agent transported by the transporter molecule does not define the invention over the prior art. Because the common special technical feature is not novel with respect to the cited reference, it is clear that the claims of Groups I-X lack a single common technical feature that defines them over the prior art.

Further, an international application containing claims to different categories of inventions will be considered to have unity of invention if the claims are drawn only to one of certain combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (see 37 CFR 1.475(b)(d)). In the instant case, the claims are drawn to multiple processes and a product, only a particular combination of which along with Group I may be considered for unity of invention, i.e., Group I and Group VI, (the first named process of using a product and the named product). Other groups are drawn to additional processes, and other combinations do not comply with the aforementioned Rules. Accordingly, a holding of lack of unity of invention is proper.

Applicant elects Group I (claims 1-45) without traverse. Applicant makes this, and reserve all rights, including those provided in 37 C.F.R. §§ 1.142(b), 1.145, and 1.146, to present claims of the same or similar scope for consideration later in this application or in another application.

Species

The Examiner further requires election of one of the following species:

a) If one of Groups I-V is elected, in claim 2,.. Applicants must elect the species of one of the preservation methods listed. This election will be applied to claim 23.

b) If one of Groups I-V is elected, Applicants must elect the species of one of the storage methods, either storage in the dry state (claim 6) or storage in the frozen state (claim 7). This election will be applied to claims 35-36.

c) If one of Groups I-V is elected, in claim 10, Applicants must elect the species of one of the biomaterials listed. This election will be applied to claim 21.

If one of Groups VI-X is elected, in claim 56, Applicants must elect the species of one of the mammalian cells listed.

d) If one of Groups I-V is elected, in claim 16, Applicants must elect the species of one of the non-metabolizable carbohydrates listed. This election will be applied to claims 29 and 40.

If one of Groups VI-X is elected, in claim 49, Applicants must elect the species of one of the non-metabolizable carbohydrates listed.

Specifically, the Examiner states:

Applicants are required, in reply to this action, to elect a single species as indicated in a) - d) above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02 (a) .

The following claim(s) are generic: 1, 15, 19, 28, 39, 46 and 48.

"The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding. special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f) (I) (B) (2), the species are not art-recognized equivalents. Each of the methods above uses different reagents and steps and has a different function and a different effect. Each of the biomaterials or cells above has a different structure, different biological, chemical and physical properties and a different function.

Because the claimed species are not art-recognized equivalents, a holding of lack of unity of invention is proper.

Applicant elects the following species:

- a) In claims 2 and 23, Applicant elects "freezing;" claims readable on this species include all of claims 1 to 45 (in particular, Applicant believes that drying is not inconsistent with freezing – for example, materials can be stored dry but at freezing temperatures);
- b) In claims 7, 35, and 36, Applicant elects "frozen state;" claims readable on this species include all of claims 1 to 45 (again, Applicant believes that dry is not exclusive of frozen);

c) In claims 10 and 21, Applicant elects "cells;" claims readable on this species include all of claims 1 to 45; and

d) In claims 16, 29 and 40, Applicant elects "3-O-methyl glucose (30MG);” claims readable on this species include 1-17, 19-30, 32-41, and 43-45.

Applicant reserves all rights and believe that generic claims are in condition for allowance.

CONCLUSION

If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, she is kindly requested to contact the undersigned.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 22727-138.

Dated: October 24, 2007

Respectfully submitted,



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